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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,625

12/27/2003

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11/30/2007

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,625	Applicant(s) SHAH, KISHORE R.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/05/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8-10, 12-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-15 and 19-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8, 10, 16, 18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims have been entered. Applicants have amended claims 1-3 and 16 and have added new claims 21-24. The supplemental amendment filed 11/05/2007 also has been fully considered. Applicants state that there is support within the '243 patent incorporated by reference for neutral monomeric units within the hydrophilic portion of the copolymer. While the examiner agrees that there is adequate support to show that there can be neutral monomeric units within the hydrophilic portion of the copolymer, the claims as noted below are not clear that there are neutral components within the hydrophilic portion.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,6,8-10,16,18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1,16 and 21 now recite that the carrier is a hydrophilic water based carrier selected from the group consisting of a solution, emulsion, dispersion, lotion, cream, petrolatum and a wax-based preparation, there is insufficient disclosure within the specification for this new limitation. Firstly petrolatum and wax-based preparations are not water-based carriers they are inorganic

carriers. Secondly the above Markush group is taken directly from the specification on page 4 lines 24-27 that describes the final form of the hydrophilic polymer film forming composition. The only description within the specification for the types of carriers is hydrophilic or hydrophobic carriers. Furthermore since applicants claimed invention within claims 1 and 16 are to a stable gel, applicants have no written description for how such a gel can further contain the above carriers such as a lotion, solution, emulsion ect.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically claims 1 and 16 both recite that the composition is a homogeneous dispersion and a homogeneous and stable gel, the claims are not clear what physical form is being claimed. It is not clear if the stable gel is also a dispersion or if the two terms are mutually exclusive and therefore limiting the claim to two different forms, in which case the meets and bounds of the claim cannot be established. To expedite the examination procedure the examiner interpreted this limitation to mean that any homogeneous gel would also meet the requirement that it is also a homogeneous dispersion.

Claims 1,16 and 21 all recite that the copolymer has at least b) one hydrophilic acidic monomer, the hydrophilic monomer contains at least about 10% acidic groups,

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from the claim construction it is not clear that (2) can contain any other type of monomer besides an acidic monomer. It is suggested by the examiner that applicants amend part (2) of the copolymer to read on a hydrophilic monomer(s) not just acidic monomers, if the above suggestion has support within the specification.

Claims 1, 16 and 21 all recite a hydrophilic water based carrier selected from the group consisting of a solution, emulsion, dispersion, lotion, cream, petrolatum and a wax-based preparation, the Markush group is limiting to the type of formulation not the carrier which should be a material substance ie water, organic solvents ect, therefore the limitation is indefinite. Also petrolatum and wax-based preparations are not water-based carriers they are inorganic carriers. Claims 1 and 16 are further indefinite because it is not clear how a composition in the form of a stable gel can contain an emulsion, solution, lotion, cream ect that are now claimed as the carriers.

Claims 1, 16 and 21 recites the limitation "hydrophilic monomer". There is insufficient antecedent basis for this limitation in the claim. Applicants have only specified earlier in each claim that (2) is a hydrophilic **acidic** monomer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,6,8,10,16,18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah (US. 5,942,243, cited by applicant) in view of Morrissey et al. (US 6,106,820), a new reasoning for a rejection over the references above were necessitated by applicants amendment and a new rejection of new claims 21-24 was necessitated by amendment.

Shah is disclosed previously in the office action dated 09/21/2006, 01/26/2007 and 07/09/2007. Shah is silent on if the copolymers disclosed within would form a homogenous dispersion in a water-based carrier. Shah also does not disclose the use of the composition as a face make up and the specific applicator for applying the topical composition.

Morrissey is disclosed in more detail in the new rejection below. Morrissey is used to primarily show that graft copolymers were well known to be capable of being dispersible within a single-phase system containing a liquid diluent such as water. See col 12 lin 5-33. Morrissey also discloses that the compositions can be formulated into several forms including creams, lotions and gels which could be used for a number of cosmetic purposes including foundations, lipstick, mascaras, eyeliner, wrinkle reducing creams and the like. See col 13 lin 47-col 14 lin 48. Morrissey also discloses that a standard brush-applicator can be used to apply the disclosed compositions. See col 18 lin 55-col 19 lin 7.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Shah discloses the same copolymers as applicants claimed invention but is

silent on if it forms a homogeneous dispersion with water while Morrissey discloses that it was already well known and understood in the art that compositions comprised of graft copolymers within the scope of applicant's claimed invention could form single phase dispersions with water. Morrissey also discloses that compositions containing such copolymers could be used for facial compositions and applying by spray and brush. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed 05/30/2007 have been fully considered but they are not persuasive.

Applicants assert that because '243 states that the polymer is water-insoluble and water swellable it is discrete and separate from the aqueous environment. Applicants further state that because of its water insolubility it is clear that it would form a non-homogeneous mixture with water. For further evidence applicants point to a passage within '243 in which two processes for compounding the drug, other ingredients and copolymer into a delivery system involves evaporation of organic solvent or mixing the ingredients in a polymer melt. Applicants contend that water being very volatile would quickly evaporate under both the above processes. Applicants lastly contend that while the copolymer and/or the compositions in '243 may be homogeneous

it cannot be assumed that their dispersion in an aqueous carrier would be homogeneous.

The relevance of the above assertions when taken in light of '243 in view of Morrissey is unclear. As described above Morrissey already disclosed that graft copolymers within the scope of applicants claims were already well known to form single phase dispersions with water or it would have at least been obvious to one to try to form such a dispersion from the disclosure of Morrissey.

Claims 1-3,6,8,10,16,18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrissey et al. (US 6,106,820). It is noted that previously a rejection over Morrissey was withdrawn, however due to applicants newly claimed subject matter the new rejection below was necessitated by amendment.

Morrissey discloses cosmetic formulations for use as facial moisturizers, lipsticks and mascaras comprised of 0.1-50% based on weight of the composition of a graft copolymer that contained A) 50 to 98% of the copolymer comprised a backbone that included acrylic acid and methacrylic acid, B) 2% to about 50% of a hydrophilic side chain that could be comprised of styrene, 50-99.9% of a carrier including water, 0.1-10% of thickeners selected from hydroxylethyl cellulose, hydroxypropyl cellulose and xanthan gum and therapeutic agents such as anti-microbials and vitamins. See abstract, col 4 lin 4-lin 47, col 6 lin 16-52, col 12 lin 11-42, col 13 lin 47-67, col 17 lin 33-56 and examples 4-5 and 10-13. The above ranges for the ingredients and copolymer components overlap applicants claimed range, therefore applicants claimed range would have been obvious to one of skill in the art because optimizing the amounts of

ingredients within a topical composition is considered routine and ordinary practice. A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974). It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) (“[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art.” See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003). Morrissey discloses that the graft copolymers can be in a single phase dispersed within the diluent (water), thus meeting applicant’s limitation of a homogeneous dispersion. Morrissey also discloses that the compositions can be formulated into several forms including as creams, lotions and gels which could be used for a number of cosmetic purposes including foundations, lipstick, mascaras, eyeliner, wrinkle reducing creams and the like. See col 13 lin 47-col 14 lin 48. Morrissey also discloses that a standard brush-applicator can be used to apply the disclosed compositions, thus meeting the limitation within claim 10. See col 18 lin 55-col 19 lin 7. Regarding claim 21 the examiner notes that the claim is drawn to a method of treating a mammalian skin with a bio-adhesive, film forming composition,

thus the steps of forming the composition (parts a and b) are essentially product by process limitations. Since the composition described by Morrissey is essentially the same as applicants the claim limitations are met because, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

No claims are allowed at this time.

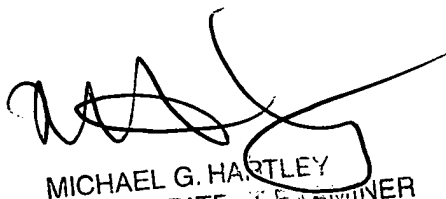
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER